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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/526,026	08/11/2005	Hideaki Yamaoka	10921.0286USWO	4688
52835 7590 02/09/2009 HAMRE, SCHUMANN, MUELLER & LARSON, P.C. P.O. BOX 2902 MINNEAPOLIS, MN 55402-0902				
EXAMINER				
MEAH, MOHAMMAD Y				
ART UNIT		PAPER NUMBER		
1652				
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02/09/2009		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/526,026

**Applicant(s)**

YAMAOKA ET AL.

**Examiner**

MD. YOUNUS MEAH

**Art Unit**

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**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 29 September 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,6-9,11-14 and 24-26 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,6-9,11-14 and 24-26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after allowance or after an Office action under Ex Parte Quayle, 25 USPQ 74, 453 O.G. 213 (Comm'r Pat. 1935). Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 9/29/08 has been entered.

With preliminary amendment of this application, the applicant, filed 09/29/2008, added new claims 25 and 26. Claims 1, 6-9, 11-14 and 24 were examined in the previous action. Claims 1, 6-9, 11-14 and 24-26 are pending.

### ***Claim Objections***

Claim 1 is objected in recitation of "hydroxycholate." The definition of hydroxycholate in the specification is repugnant to one of ordinary skill in the art. Because hydroxycholate defined in the specification comprise various cholate derivatives including cholate itself (cholate contains hydroxyl group).Appropriate correction is required.

### ***Claim Rejections***

35 U.S.C 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claim 1 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1: the recitation " hydroxy-cholate"- makes the claim unclear. Because hydroxycholate defined in the specification comprises various cholate derivatives including cholate itself, therefore one of ordinary skill in the art can understand the metes and bound of the claim.

***CLAIM Rejection - 35 U.S.C 103a***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Rejection of Claims 1, 6-9, 11-14 and 24 under 35 U.S.C. 103(b) unpatentable over Shimomura et al ( Anal biochem 1986 vol 153, pp 126-131) in view of Sode et al. (WO 02/36779, English translation in US 2004/0023330) is withdrawn. .

Claims 1, 6-9, 11-14 and 24-26 are rejected under 35 U.S.C. 103(b) by Shimomura et al ( Anal biochem 1986 vol 153, pp 126-131) in view of Sode et al. (WO

02/36779, English translation in US 2004/0023330) and Amersham catalog 1999, pages 520, 523 and 527)

Claims 1, 6-9, 11-14 and 24-26 are directed to the purification of *Burkholderia* GDH protein comprising  $\alpha$ ,  $\beta$ ,  $\gamma$  subunits using liquid chromatography comprising ion exchange (resin comprising quaternary ammonium group) and using eluent containing cholate.

Shimomura et al teach the purification of Cytochrome bc (a protein having electron transfer and GDH unit) protein using liquid chromatography comprising phenyl-sepharose and ion exchange (DEAE; diethylaminoethyl) sepharose column, wherein eluent is applied at constant gradient containing 0.25% cholate.

Sode teach GDH protein from microorganism *Burkholderia Cepacia* comprising  $\alpha$ ,  $\beta$ ,  $\gamma$  subunit and teaches expression of said protein in *E. coli* and the purification of said GDH protein by ion-exchange chromatography using DEAE-Toyopearl column using a buffer at pH 8.0 ( a non-acidic pH). However, Sode et al. do not teach the elution of said columns with a hydroxyl cholate gradient nor teach chromatography using quaternary ammonium group comprising tetra-alkyl or tetra-aryl substituted ammonium ion exchanger.

Q-sepharose are ion-exchange column comprising a quaternary ammonium moiety and commercially available from Amersham (see Amersham Catalog 1999, page 523). Advantageous use Q-sepharose a anion exchanger in protein purification is

well documented, such as high flow, high capacity, reproducibility, industrial scale application and commercial availability (see catalog Amersham 1999, pages 520, 523). Therefore Q-sepharose has advantages over other DEAE column, such as wide pH ranges, high resolution, and high capacity for the protein to be separated in high salt concentration.

Cholate is used as eluent for the purification of different cytochrome type proteins because it facilitates hydrophobic-interaction and behaves as detergent. Protein is adsorbed in the column matrix and cholate act as detergent to dissolve it (see Imai et al J. Biochem 1976, pp 267-276, page 274 from IDS, Shimomura et al Abstract)

As such it would have been obvious to one of ordinary skill in the art to obtain GDH protein comprising  $\alpha$ ,  $\beta$ ,  $\gamma$  subunit from microorganism *Burkholderia Cepacia* or said GDH produced by transformant such as *E. coli* taught by Sode and use the method of purification using ion exchange column with Q-sheparose, wherein eluent is applied at constant gradient containing 0.25% cholate (a high salt concentration Q sepharose is preferred, instead of sodium chloride) as taught by Shimomura et al.

Applicants' arguments become moot because prior 103(a) rejection is withdrawn.

### **Conclusion**

Claims 1, 6-9, 11-14 and 24-26 are rejected. No claim is allowed

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mohammad Meah whose telephone number is 571-272-1261. The examiner can normally be reached on 8:30-5PM.  
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, NASHAAT T NASHED can be reached on 571-272-0934. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Mohammad Younus Meah,

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